DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

August 11, 2005

FILE COPY

Peter S. Reichertz
Sonnenchein, Nath & Rosenthal, LLP
1301 K Street N.W.
Suite 600, East Tower
Washington, DC 20005

Dear Mr. Reichertz:

Your petition requesting the Food and Drug Administration to determine that PHENERGAN (Promethazine hydrochloride) tablets 12.5mg and 50mg, were voluntarily withdrawn by Wyeth Pharmaceuticals, Inc., for reasons other than safety and effectiveness, was received by this office on 08/11/2005. It was assigned docket number 2005P-0319/CP1 and it was filed on 08/11/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega

Gloria Ortega, Deputy Director
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0319

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